History

of the

U.S. Food and Drug Administration

Interviewee: Richard Merrill, Esquire

Interviewer: Suzanne W. Junod, Ph.D.
Robert A. Tucker

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Place: Rockville, MD

Richard A. Merrill

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TAPE 1, SIDE A

This is another in our series of FDA oral history interviews. Today is July 12, 2004, and our interview is with Richard A. Merrill, former FDA Chief Counsel, currently a professor of law at the University of Virginia. The interview is taking place in the Parklawn Building in Rockville, Maryland. Included in the interview are Dr. Suzanne White Junod and Robert Tucker of the History Office.

RT: Mr. Merrill, we like to begin these interviews with a brief resume of your personal history, where you were born, educated, and your career experience in brief, prior to your joining the Food and Drug Administration. So if you would proceed in that manner, we will begin.

RM: I was born in Logan, Utah, in 1937. Logan is the home of Utah State University, where my father was a member of the faculty and an administrator for almost forty-five years. I was educated in the Logan city schools and Logan High School and was persuaded by the librarian at Logan High School to apply to go to college across the country, at Columbia in New York, where, by coincidence, my father had done some of his graduate work, so we had a connection there.

RT: Was your father also in law?

RM: My father was a political scientist -- historian and political scientist. But I'm sure that there was enough linkage. He was interested in the activities of people like Senator Reed Smoot, who was a prominent Republican leader in the Senate in the early part of the century. Senator Smoot was the focus of my father's dissertation.

SJ: Smoot, originator of the Smoot tariff?

RM: Yes. And so my father's interest in politics and people in politics sort of meshed with what became my later interest in law and the law of governing political organizations and the operations of government bodies like the Food and Drug Administration.

RT: When you went to Columbia was your objective at that time to study law?

RM: I had no idea at that time. I went to Columbia because my librarian and my parents said it was a good place to go. It had then, and still has, a famous core curriculum for the first two years, a strong liberal arts, classical curriculum, and I'm sure that was an attraction. Law I think was not very much on my mental horizon at the time.

I quickly became infatuated with history courses there and took almost half of the credits that are required for graduation in American history from five history faculty members. And when I approached graduation, it was my clear intention to go to graduate

school in American history either at Princeton or at the University of Wisconsin, which had a particularly strong American history program at the time. And I had indeed won a fellowship to support graduate study, but the opportunity to go to Oxford intervened. I was selected as a Rhodes Scholar from Utah and headed off to Oxford to study what they labeled modern history.

RT: What year, Richard, did you graduate from Columbia?

RM: Nineteen fifty-nine.

SJ: And during your time at Columbia, they had some strong American historians at that point.

RM: Well, probably the most famous was a man I never studied with, Richard Hofstetter, but a number of his protégés taught me, one by the name of Walter Metzger, and James Shenton in particular, and also some European historians, Fritz Stern, who's probably the most notable of those, and Peter Gay, who later moved to and is still at Yale and is a cultural historian. Probably the most memorable course I had was a historiography seminar from Shenton and Gay. Twelve of us met once a week around four or four-thirty in the afternoon, and were served sherry and sweets as we proceeded to discuss Thucydides or some other major historical figure and listened to these two great minds ruminate about what they'd read and thought about the work.

RT: And your degrees from Columbia were in what?

RM: From Columbia, I earned an AB degree in American history. And from Oxford, I have a BA and an MA, which is really a phony degree and one you acquire by survival and payment of college dues for two years following the ending of your BA degree. So I can report that I have a BA and an MA from Oxford, but everybody understands that an MA is not an earned degree but a degree conferred for longevity.

And it was at Oxford that I made the decision that I wanted to go to law school, partly because, to be perfectly candid, although I loved Oxford and liked much of the academic experience there, I really didn't fancy myself being a historian. I could see that was a long and uncertain career path, while law was the clear ally of American history and it could be accomplished in three years, no uncertainties, and so I applied to law school and came back to the States to go, as it turned out, to Columbia.

RT: You returned to Columbia for the . . .

RM: For the law degree. That was 1961.

Simultaneously, I got married to the woman I'd been engaged to while at Oxford, who grew up in Salt Lake City and was training to be an elementary or secondary school teacher, at least initially, in order to support us while I went off to law school. So she got a job in the White Plains school district north of Manhattan, and we lived next to Columbia. I did three years of law and, as predicted, at the end of three years, I had the degree, no dissertation required, no ABD or anything.

RT: After your degree, did you enter into a law firm or practice?

RM: A year later. First, I was fortunate to get a judicial clerkship with Judge Carl McGowen, who was a member of the D.C. Circuit Court of Appeals here in Washington, and I worked for him for one year as his law clerk, drafting opinions, cite-checking opinions, helping him with the research on cases and also on speeches and lectures, of which he did a not-inconsiderable amount. McGowen had been counsel to Adlai Stevenson when Stevenson was governor of Illinois, and he was, accordingly, close to the Democratic Party in the state of Illinois. He was sponsored by Paul Douglas, a senator from Illinois, to the D.C. Circuit, and became, I think, without much debate, one of the most admired and respected circuit judges in the country over the course of the next twenty years. And it was after that clerkship year that I joined a law firm.

I went to Covington & Burling in Washington as an associate, where I worked for four years before deciding to head south to become a law teacher. And it was at Covington & Burling that I became a food and drug lawyer. Not by choice, I guess I have to admit, but by necessity, because I was assigned to work with Tommy Austern, who was a famous figure in the field, and one of his mentees, Stan Temko, who had hired me from Columbia. They did food and drug work and, as a result, I did food and drug work.

SJ: Now, we never got an interview with Thomas Austern, but he's one of the people whose published work I know pretty well, and he fascinates me in some respects. Tell us

a little bit about Tommy Austern, because you're one of the few people who still remembers working with him.

RM: Well, he was an enormously smart man, crusty, not much in the way of style, not much in the way of interpersonal skills. However, he had enough to get by. But he was not shy about telling clients that they didn't know what they were talking about. He had an enormous depth of understanding of the field of food and drug regulation, its historical underpinnings, the factual controversies that gave rise to new regulatory policies or legislation. And he was sought after by many of the major associations of companies whose products FDA regulates: pharmaceuticals, food.

The work I did for him involved beer. The United States Brewers' Association came to him when they had experienced, or some of their members had experienced, some health effects associated with two or three brands of beer that had used cobalt salts as a cosmetic agent to enhance the foam appeal of beer. It turned out that if you consumed very, very large amounts of cobalt-treated beer, you increased your risk of a kind of cardiomyopathy quite significantly. And this was seen in a number of brewery workers in Canada who drank beer on the job, as they were permitted to do, copious amounts. I am fond of telling my students, just as an example of the relationship between dose and effects, that some of the brewery workers in Canada were consuming anywhere from thirty-six to forty-eight bottles a day.

Anyway, this brought the Brewers' Association to us saying, "We've got a problem. We need you to help us solve it. It's a problem at a number of levels. The FDA is going to be interested, even though FDA was not actively regulating, never had

been actively regulating beer or alcoholic beverages. We have IRS problems because beer is a regulated, a taxed product. We may have product liability problems. We certainly have public relations problems." So Austern took on the brewers, and I was summoned to Austern's desk side to be his assistant in handling that account and spent a lot of time with it.

My wife's recollection of those days is not happy. She thought that Austern was oppressive and demanding and churlish in dealing with anybody else, including her, and she was probably right in many respects. He was not an easy person to work for, but he was a remarkable mentor, and maybe intentionally so.

What impressed me most was the care he took with legal presentations for a meeting. He rarely went into a meeting without thinking through exactly how he wanted the conversation to flow and how he wanted the deliberations to come out. We spent a lot of time late in the afternoon and early in the evening in a sense drafting the script that he wanted to play out. He had all of the words he wanted to speak written down in advance of the next day's meeting. The importance of preparation for a presentation was driven home very, very strongly. Though Austern would often walk into a room where people were not inclined to be receptive to the kind of advice he was going to provide, he rarely came out of the room without acceptance of the advice that he thought they ought to follow.

The brewers, to a large extent, have the strong imprint of the German brewing industry. These were Nordic types that were in the major brewing companies across the United States at that time, and Austern was a New York Jew. And there was a cultural gulf there that he had to bridge, and he knew he had to bridge it. But he acquired their

respect, and I suspect there were even one or two who would have said that he carried their admiration and affection. But affection was not the trait that he traded on. It was respect and smarts.

SJ: So was Peter Hutt at Covington & Burling?

RM: Peter Hutt was another of Austern's mentees. And he and I were drawn together. We did no work in common with or for Austern, a little work in common with Stan Temko.

But we did a lot of work jointly on a series of cases where the American Civil Liberties Union was challenging the common practice across the United States of incarcerating drunks, whose very presence bothered people in local communities. The ACLU was pressing the argument that a chronic alcoholic has no capacity to control his drunkenness; he may have capacity to control some behavior that results, but not the state of being drunk. And it's a violation of the Eighth Amendment to prosecute and convict somebody for conduct that is not involuntary.

We participated in a number of cases as *amicus* cases in the Fourth Circuit Court of Appeals. I remember going to Richmond for an argument there of cases in the Fourth Circuit. I also remember a case that came out of the State of Texas called *Powell v. Texas*. It was decided by the Supreme Court in an opinion by Justice Thurgood Marshall, which went against the argument that we were making. But it was whether we failed in the end because there are success in a number of lower courts in establishing the Constitutional proposition forcing many communities and states to rethink what they

were doing about public drunkenness. And many backed off the historic practice of just collecting drunks and tossing them in jail every night, and they began to provide something more in the way of treatment or prevention. I dare say that those efforts have not entirely been successful and probably, if we looked at them closely today, we would say they looked pretty puny in comparison to the source of the problem.

RT: To regress a moment to what you mentioned about the beer industry itself regarding the copious consumption by employees of alcohol, was that an alcohol concern that the industry had about their own personnel?

RM: It was not raised in conversations to which I was privy. That was not an issue on which the brewers thought they had a common position, and it's certainly not an issue that they sought Austern's advice about.

RT: It was the food-additive aspect.

RM: Exactly, it was the food-additive aspect. And I think that the facts surrounding the experience of the copious beer drinkers from Canada are pretty peculiar. I don't have any doubt that it was common practice in the American breweries to allow workers to sample the product that they were working on. But I would venture that there's a lot more effort taken to discipline that activity, maybe even to curb it now, in the self-interest of the brewing companies, because I'm sure that by the end of the day, people who were drinking during the day are not as efficient workers and are probably a risk to

other workers who are not imbibing. And there were some potential liability concerns there.

SJ: Well, did the beer industry abandon using that particular additive?

RM: Yes. Cobalt was dropped like a hot potato. But what we really did for the brewers was devise a system of industry oversight of the ingredients they would be putting in beer and to try to put the Food and Drug Administration in the position of knowing what was going into beer by the industry rather than by individual brewery name. Our submission was generic, you might say, that is, to establish a list of ingredients used by one or more companies, rather than by a specific company.

RT: Was the agency, the Food and Drug Administration, later involved in this concern or problem?

RM: Our presentations to the FDA as to what the industry was doing, and the core of the industry position that Austern got them to agree to was that members of the association would use only ingredients that would satisfy the requirements of the Food and Drug Act. Some of the ingredients they were then using, and I'm sure are using today, are approved additives, regulated food additives. Some undoubtedly are prior sanctioned. They've been used for as long as the memory of man runs, or at least as long as the relevant memory of man runs. But there is no expectation on the part of the brewing industry that FDA would abandon its passive posture and say, "We're going to assert regulatory

jurisdiction here." The idea was to make the agency comfortable enough with what was happening that they needn't assert regulatory jurisdiction.

RT: It's interesting and maybe ironic that in the earliest days of food and drug regulation, there was interest, at least by Dr. Harvey W. Wiley, in the adulteration of whiskeys.

RM: Yes.

RT: So it's come around again.

RM: Dr. Wiley had a sort of schizophrenic view of the role the agency should take in the regulation of the labeling and content of alcoholic beverages.

SJ: He needed the support of the Women's Christian Temperance Union (WCTU). Austern was also instrumental in setting up the food-standard hearings that resulted in the standardization of a lot of the early foods, sort of what we considered staple foods.

RM: Yes, that's right.

I was never involved in working with him on those matters, and I never was clear whether Austern became involved because he was an enthusiast for the standardization of foods or whether he became involved because his clients were concerned about the agency's exercise of its new authority to adopt standards of identity.

SJ: I agree. Many manufacturers were leery of the process.

RM: I think that's probably right, although Austern was a strong believer in the administrative process that the law prescribed for the adoption of food standards, with an evidentiary hearing as the central element. In the face of increasing skepticism within the agency itself that this process didn't make any sense at all.

SJ: And he turned out to be correct, I think, later. On behalf of his clients, though, he was able to get many ingredients put in the standards. Again, I think he was very worried about the intent -- was this even the best way to go about it, prior to passage of the Food Additives Amendment.

RM: I think that's probably right. I draw those inferences from reading what he wrote rather than from any conversation we had.

Simultaneously, while I was there, the FDA was mired in two major food-standards proceedings. One involved dietary supplements, which was in part a food-standards proceeding and in part a labeling proceeding under Section 403(j) of the statute. The other was the famous peanut-butter hearing, where a colleague of mine with whom I'd gone to law school spent the last three years of his private-practice career working on peanut butter. He said, "That's enough for me. I'm going to go off and do something else," and he, too, became a law teacher.

SJ: Kaplan, Alan Kaplan?

RM: No, Richard Cappalli. I don't think he ever taught a course about food and drug regulation. I don't think that was a topic that interested him. I think he became a civil-procedure teacher.

RT: As you moved ahead in your career, was there anything else that should be mentioned during your law firm association with Covington & Burling?

RM: I think we've covered that. The two major activities that occupied me for most of the time were the work for the U.S. Brewers' Association with Austern and other food and drug projects with lawyers in the firm, as well as the work with Peter Hutt on the ACLU campaign against prosecutions for public drunkenness.

About three years into my five at the firm -- that would be about 1968 -- I decided that I wanted to try the law-teaching path, something that I had considered at the end of my clerkship. Carl McGowen, the judge for whom I clerked, had been a law teacher at one time, and he knew a lot of law teachers. They periodically would come by his chambers in Washington just to chat with him, and not infrequently he would say, "You ought to go talk with this young fellow who has just come to work for me. He might be a law teacher someday." I had talked quite seriously with the dean at Iowa, the dean of Arizona State, who'd come from Northwestern to be the dean there, and the dean of Stanford Law School. But I decided that I didn't want to leave Washington. So I put such overtures aside, never quite closing the door. But it was always in the back of my

mind that maybe teaching was going to be a more satisfying way to make use of my law degree. And so in 1968, as we would put it now, I went on the market.

Now, you would register with Association of American Law Schools and join 973 other individuals who were also on the market as potential law teachers whose credentials would be sent to the 165 accredited American law schools. In my day, however, you wrote a discreet letter or asked a mentor, maybe a judge like McGowen or a law teacher, to put word out among their friends in other law schools that you were in the market. Then you hoped that people would pick up the telephone and say, "Could we talk with you?"

That's what I did. And I got some telephone calls and ended up talking closely with six law schools, three in the West and three in the East. The schools in the East were the ones that really got our attention because we by then had concluded that we wanted to settle in the Washington, D.C. area, or at least not too far from it. I received offers from Columbia, Pennsylvania, and Virginia. And I liked Virginia best because I liked the people there better, and I thought it was a school that had real upward potential, not as well recognized nationally as Penn or certainly my alma mater, Columbia, yet Columbia by that time did not appeal to us because we had a child and Columbia meant New York City. New York City in the late 1960s didn't have anything like the appeal that it now has for my kids or for me, for that matter, now. So we ruled Columbia out on geographic grounds, and then the choice was Penn or Virginia, and I liked the Virginia faculty more. I felt more comfortable. My wife finally got over the idea that we were moving south of the Mason-Dixon Line, something that she had vowed she would never do. She had earlier vowed that she would never live in a city smaller than Salt Lake. So

I had two immediate strikes against Virginia, but she ended up liking the people there a lot. Within a year we were very sure we'd made the right choice. I think my wife would say emphatically that it was the right choice from her perspective as well as from my professional perspective. So I go off to Charlottesville in the fall of 1969.

RT: Did you work on the faculty until you took the sabbatical?

RM: I taught full time for five years and was an administrator for a sixth. I was associate dean during the '74 to '75 year. But in '74, late, I guess it would be, I got a call from Peter Hutt, my former sidekick at Covington.

TAPE 1, SIDE B

RT: Dick, you were just speaking about your call from Peter Hutt.

RM: He called me sometime in 1974 -- I would reckon it to be October maybe -- and said, "I'm going to be leaving this job in the next six months. Would you like me to put your name in for consideration to succeed me?" And, after consultation with my wife -- by now we had a second child, both of whom were in school -- we decided that if the opportunity came, it would be worth doing. So I said, "Yes, put my name in." It was a much lower-key process then. I don't know who else had their name in. I was never interviewed by the White House. I was never interviewed by the Department of Justice.

I'm sure I must have had to fill out some form with some information. I also

recall that we had to pay attention to the problems associated with some stock that my wife had inherited from an aunt, which included Pfizer and Safeway, companies regulated by FDA, and, unhappily, from our financial well-being standpoint, we had to liquidate those holdings. They were not very big then. It was not a huge amount, but they would have been much larger now. But anyway, there was that modest financial sacrifice.

That's the only issue covered by the personal disclosure forms that I had to resolve for high-level government service in order to be considered for judicial appointments then, and the process that one has to go through now is a much different process than the one I went through then.

I had half-day interviews with the then-general counsel of the Department of Health, Education and Welfare, John Rhinelander. And I met his deputy, St. John Barrett, for an hour and a half. I'm sure I had a conversation, but I don't now recall whether it was before or after my appointment, with the then-commissioner, Mac Schmidt, who was to be my client and boss. It turned out we had a lot in common. I discovered that he grew up in Ogden, Utah, about 45 miles south of my home in Logan, Utah. The chances of that happening are pretty slim. We knew a lot of people in common, and there was immediate rapport. Dr. Schmidt was also an academic.

So that is the extent of the selection process. Peter called back to say that Rhinelander had said he would make me the offer. And I don't even remember what John asked or demanded. I have no doubt that we talked about how long would I do the job, and I'm sure I said, "As long as the University will give me leave," which was, as we both understood at the time, two years, maybe slightly more. So we came to FDA with

the expectation that if I returned to teaching and went back to Charlottesville, it would be two years after arriving. We were here for twenty-six or twenty-seven months rather than twenty-four.

RT: Were you assured by the University that you would come back at the same level?

RM: Yes, if I came back within that two-year period. There was a well-established though unwritten faculty policy -- and really it was the faculty that had to acquiesce at the dean's recommendation.

RT: Your experience as chief counsel of an agency of this stature no doubt was desirable for the university as well, wasn't it?

RM: Probably. I'm hesitant to confirm that too enthusiastically. I don't remember because I wasn't privy to the discussion of the faculty or how long it took. It might have been a five-minute discussion. I think there would surely be colleagues who would say, "Yes, Merrill teaches administrative law and food and drug law. What better job could there be for somebody with those interests?"

RT: Since you returned, Dick, has your chief counsel experience here been helpful to you as a professor?

RM: Yes, without question. The follow-up question might well be, just how, and I

would have a harder time pinpointing that. That is, I might be able to go through the materials that I use in class and the examples that I use in class and identify insights that are a product of the experience rather than a product of reading about a case or studying what somebody else did. But I think the experience permeated my approach in the classroom in subtle and not easily definable ways. I don't spend much time when I'm talking to students about things, such as telling war stories. I occasionally will use an example from FDA. My casebook on administrative law has a number of FDA examples, but so do other casebooks on administrative law. These are examples that have general application, and anybody who teaches the subject would use them, whether or not he or she had any experience at FDA, so the impact is profound but subtle, and that's not a contradiction.

SJ: Now, when you were teaching at UVA in the late '60s, early '70s, was there a lot of interest in food and drug law at that point?

RM: No.

SJ: You created it from scratch?

RM: Well, I created as much as there is, although I think that the visibility of FDA and the controversy surrounding the issues it deals with make a difference. But food and drug law is still a narrow field of interest in law school. Some of my students find their way into the field. I have five former students working now in the Office of General

Counsel and two former Covington associates who worked for me who are working for Dan Troy in the Office of Chief Counsel. But I suspect that, of those seven, probably only two or three took Food and Drug Law while they were in law school. Along with several other government offices, they interviewed with the Chief Counsel's office, where people said, "The work there is better, the people are better, they're more congenial. It's going to be a more satisfying place to work." There are a lot more courses in food and drug law now, probably as many as 40 law schools that teach food and drug law. When I started, I had a class of five students. In a big year, I will get thirty or thirty-two or -three. But in 1980, there might have been eight or nine law schools that taught it, and maybe two taught it using resident faculty like me. I'm quite a rarity. Margaret Gilhooley is another example of somebody who is a full-time legal academic who teaches and specializes in food and drug law. Most of the people who teach the subject teach it on the side.

RT: Considering your tenure here in the agency, you served at a time when several rather important things were happening. Maybe we can cover some of those from your perspective. There was some discussion, as I recall, about the Delaney Amendment and how that might be reforming. Does that ring a bell?

RM: Absolutely. I guess I'd generalize it and say there were concerns about unsafe food additives or additives to food -- and I would include in that color additives, because red #2 the high-profile target of controversy in that period. The question of the adequacy of the safety testing for a variety of food additives was a recurrent issue.

Delaney was much on the scene of those debates because often the controversy was over whether or not the tests that had been done showed an additive to cause cancer in animals or whether tests should have been done to find out whether it did. And the implication was, if the answer were yes to the first or do we need to do it, and if the answer turns out to be yes in the second, then the law says the additive can't be approved. Much of the debate about food-additive safety was carried on in the shadow of the operation of the Delaney clause. In a couple of cases, it was the central issue. DES [dietyl stilbesterol] as a growth promoter in livestock animals and, most notably, I think, saccharin as a direct additive to human food, including a lot of dietary products, including soft drinks, non-caloric soft drinks.

I suppose the most visible, enduring target of debate around Delaney was the saccharin case, which had been burbling along in the agency for six or seven years, until late '75 or early '76. It was late '76 or early '77 when the Canadian government reported that researchers there concluded yet another animal-feeding study of saccharin and had concluded that saccharin indeed was a bladder carcinogen in the rat. That set in motion a flurry of activity and debate and consultation within the U.S. government, and very quickly led to a decision by FDA to propose the banning of saccharin under the Delaney clause.

RT: In addition to the intended or known impact of food additives, there was also concern, I believe, about environmental carcinogens. Were you involved in some of those issues? I think you made a presentation one time about the regulation of environmental carcinogens.

RM: Let me try to reconstruct what I recall.

After leaving the FDA, I did a lot of thinking and writing about regulation of carcinogens, including a major study for the U.S. Administrative Conference, which looked at FDA, OSHA [Occupational Safety & Health Administration], EPA [Environmental Protection Agency], and the Consumer Product Safety Commission. The government was, on a number of fronts, becoming increasingly concerned about the possible impact of environmental carcinogens. This sounds like we're talking about pollutants, things that accidentally get into the environment. But I use the terminology, and I think many others do, to describe chemicals that are man-made to which we are exposed in a number of ways, purposeful and accidental. So I would classify saccharin as an environmental carcinogen; just as red #2 is an environmental carcinogen. They happen to be in the purposeful category. PCB's [polychlorinated biphenyls] is a non-purposeful environmental carcinogen. A pesticide that causes cancer in animals and makes its way into the food supply by spraying on the food is a purposeful carcinogen. However, if it makes its way into the food supply because it drifts to a neighboring field, it's an accidental carcinogen. The impact on health of such chemicals was a preoccupying problem for government regulators for the next decade, maybe longer, and examples periodically surfaced here at FDA. Saccharin is one; red #2 is another; DES is a third. Aflatoxin in peanuts or on grains was yet another example of a putative carcinogen that required regulatory attention.

The interesting feature of FDA's responsibility in this area was that the law was not uniform with respect to the various ways in which carcinogens made their way into

the food supply. Purposeful ones are subject to the Delaney clause because they're food additives; accidental ones are not subject to the Delaney clause because they are environmental carcinogens or pesticide residues or something else. Thus, while there was a similarity -- you had a chemical about which somebody said we now have a test that shows it causes cancer -- you couldn't say, "Well, there's an automatic legal response to that." You have to say, "What kind of chemical is it? What is it used for, and how does it make its way into food?" Then you have a series of quite different legal responses. This made for a lot of interesting work for lawyers.

RT: Since the initial enactment of the Delaney clause, there were many advances in sensitivity of instrumentation, which changed the whole scene again, didn't it?

RM: It did. That was an issue that was attracting attention before I got here, three or four years before; beginning when DES residues were found in the edible portions of treated animals. That is, in animals that had received DES as an implant or a feed additive. The statute, as you both know, covering animal drugs adds a caveat to the Delaney clause which says, in substance: You can use it in animals, and if you don't find any of it in the edible portions of the animal, it's not forbidden even if it's a carcinogen. This language immediately focused attention on the methods FDA should use for finding residues. At the end of the day, the agency ended up with a very sophisticated methodology for specifying how good a company's proposed test method had to be in order to maintain the approval, or gain the approval of an animal drug that is positive in tests for carcinogenicity. This was the so-called "sensitivity-of-method" document. It

was first proposed, I think, in 1973, re-proposed in 1975, and has gone through a number of iterations. It still represents, I think, the best thinking of the agency about how you address the question of very low levels of carcinogens in the food supply.

RT: Beyond the issue of carcinogenicity in foods, there were also many foods that were adulterated in other ways, which I think brought forth an issue about misbranding of adulterated foods.

RM: It did. I have to confess that that was not an issue that came across my desk during the time that I was here. At least I don't recall it being something that I worked on. It had a niche in my caseload with Peter Hutt, but it's because Peter put it there, not because I had immediate experience with wrestling with the question.

RT: That may be more a matter of a field manager's interest.

RM: It is. Not long after I left the agency, the issue of aflatoxin contamination of corn grown in the southeast part of the United States surfaced. One facet of that issue was whether or not you could blend below-tolerance with above-tolerance corn to yield a marketable product. And the economic implications for corn growers and for cattle producers who depended on corn for feed was quite significant. Thus, the agency had to wrestle with whether or not it made sense in the circumstances to continue to adhere to this longstanding policy that you can't blend adulterated with unadulterated products to get a product that is marketable.

RT: You touched exactly on what I was referring to.

RM: Yes. But I know the case as a teacher-scholar, not as a former FDA lawyer.

RT: In the matter of human-use drugs, I think concern arose about policies on drug exportation. In other words, was the agency liable for responsibility to regulate exports that might not conform with the receiving country's standards?

RM: That, too, is an issue that I know about as a result of my teaching rather than as a product of my work when I was here. It was just beginning to surface. The issue was not just the export of the drug but the export of the job. Manufacturers said the process of getting a product approved by FDA was so long and so costly that they were beginning to rethink decisions about where to locate manufacturing facilities. If we locate them here and we get an approval in Germany, we still can't ship the drug to Germany, where it's approved, until it's also approved in the United States. So one solution was to change the law to make it easier to export, which was eventually done several years later.

An issue that did engage a lot of my attention during the time I was here was the FDA drug-approval process. The thing I remember most vividly about my early weeks at the agency was the image of Commissioner Schmidt and Dr. [Richard] Crout, the head of the Bureau of Drugs, and several other high-ranking officials at the series of hearings chaired by Senator Edward Kennedy. The hearings focused generally, though not exclusively, on the drug-approval process. The central focus of the hearings was not,

though, on the slowness of the process but on whether the process was sufficiently protective of users of drugs that might be unsafe if not adequately tested. Kennedy at one point staged a hearing in which several current drug reviewers testified. The general gist of their testimony was that "we are under undue pressure from management to speed up this process and ignore questions about the safety of drugs." That got a lot of press attention. Leslie Stahl, who came on television for the first time, was covering those hearings for CBS. Kennedy himself drew a lot of television attention, and I think FDA management spent more time thinking about, worrying about, responding to the Kennedy hearings than it spent on any other single topic during this time period. And as a consequence, I, too, spent a lot of time thinking about how FDA management should deal with the Center for Drugs, with the congressional committee, and then, most centrally, how to deal with the special investigatory entity that was set up by the Secretary of Health, Education and Welfare -- it hadn't become HHS yet -- in response to the Kennedy hearings.

Kennedy's leverage was sufficient to persuade David Matthews, who was the HEW Secretary, following Casper Weinberger, to set up something called the Dorsen Panel, although it was originally the Chalmers Panel. Tom Chalmers of Mt. Sinai in New York was the original chair, but he resigned under pressure because he was thought to be insufficiently critical of FDA. The panel chairmanship fell to Norman Dorsen, a very distinguished member of the NYU law faculty. Dorsen and five colleagues -- maybe four by the time that the reports had all been compiled -- after an almost year-long investigation reported that there was a lot wrong with the drug-approval process. It was not sufficiently critical; it was too subject to informal manufacturer influence; and a host

of other criticisms. It would be fair to say that the Dorsen Panel report highlighted a number of the recurrent complaints about the drug-approval process that animated the subsequent legislative debate and had some influence on legislation as late as the FDAMA [Food and Drug Modernization Act] in 1997.

But it was a quite different kind of debate about drug approvals. The Kennedy hearings were billed as the first hearings on "drug lag," but they didn't talk about lags, they talked about drugs. And it was not until the early 1980s that serious people, including people in Congress, began to warn about the health costs of a slow, deliberate, and extremely careful drug-review process. Ultimately, we know, the most important legislative response was user fees, but they don't come until fifteen years later. So "drug lag" is a concern to the industry, for sure, and it is a concern to some academic authors, including Henry Grabowski at Duke and Sam Pelzman at Chicago, who attempted to highlight what the costs are of being slower and more fastidious than any other drug agency in the world.

But during my time here the burning concern was, how do we respond to Kennedy? How do we make sure that people are not unduly pressured? How do we make sure that pharmaceutical manufacturers don't exercise undue influence over the people who are looking at their firm's drug applications?

SJ: This followed on a series of drug cases that the Supreme Court ruled on while Peter Hutt was Chief Counsel. Was there a direct link?

RM: No. I think it's quite accidental. Those cases are very important, however, and I

just spent a lot of my time re-reading the decisions and the briefs as they shed light on FDA's rulemaking authority. But those cases really grow out of the 1962 Drug Amendments. The Amendments led FDA to establish a process, relying on the recommendations of the National Academy of Sciences, to assess the effectiveness of drugs that had been approved pre-'62 under the 1938 act.

One of the unusual things about those cases was, first, that there were actually five cases before the Supreme Court simultaneously. They were consolidated for purposes of argument. And the government's first brief is an overview of what Congress did in '62 and what processes it put in place and what obligations it imposed on the agency. Then it discussed the practical difficulties of fulfilling the congressional expectations. Finally, at the end of the brief, the government provided a little discussion of the law. FDA prevailed on all of the important issues in those cases, the two most important being that you don't have to give a hearing to somebody who claims the statute requires a hearing but can't show that there are any facts to be resolved in the hearing. The other was that FDA has authority administratively to determine whether a drug is a new drug which required approval. That authority extended to drugs that had never been subject to NDAs [new drug applications] as well as to drugs that at one time had been subject to NDAs but no longer were considered by the manufacturer, and perhaps FDA, to be new drugs. I think Peter Hutt would say -- and he's probably right -- that the confirmation of FDA's primary jurisdiction to determine the legal status of a regulated product was the key holding of those cases. The right-to-hearing issue was a big issue as a practical matter, but the law on which the courts relied had been established by other agencies prior to that time. Really the FDA paradigm didn't present a new set of issues

for the court.

RT: During that regulatory process or period, there were many hearings, and I know you were involved in some of them with the commissioner.

RM: When I retired from the agency, I was given a bound set, courtesy of Gerry Meyer, of all of the hearings in which I participated. Commissioner Don Kennedy also gave me one of two charts that he had prepared to demonstrate to skeptical audiences how many hearings FDA faced.

TAPE 2, SIDE A

RT: We've changed the tape. Please continue.

RM: Sure. We were talking about the number of hearings that FDA was invited to or subjected to. I don't think this has changed very much, but it seemed dramatic at the time. Don Kennedy had prepared, for show-and-tell purposes to various audiences, two charts, one depicting the first session of Congress when he was Commissioner, and the other depicting the second session. Each one shows the number of hearings held by various committees in the House and Senate, and lists which FDA officials appeared. The message is that you could spend your life doing nothing but attending hearings, and nobody would be minding the store. This, of course, was the purpose of the message.

RT: During that period, was there a change in political administrations?

RM: Yes. I think the truth is that that the change slowed the pace of hearings slightly. It certainly changed the tenor. When I came, [Gerald R.] Ford was President, and the Democrats, as they had for many years before and several years following, controlled both houses of Congress. They held the chairs of the relevant oversight committees and legislative committees. And it always happens that a legislative body managed by leaders from one party will be harsher on leaders of the other party that are in charge of the Executive Branch. I don't think there's any doubt that Senator Kennedy thought there was mileage to be gained out of embarrassing a Republican administration, e.g., with respect to the issues ultimately addressed in the Dorsen report.

When the Democrats won the White House, when Jimmy Carter defeated Gerald Ford, the game is changed. There was a lot of interest in having Kennedy testify because he's a new boy and because members of Congress were interested in sharing their views of what the agency should be doing. But Don Kennedy was much more comfortable than Mac Schmidt was and he was treated more gently. Mac Schmidt was subjected to the equivalent of the "perp walk" when he came into a congressional hearing, you know, someone on his way to jail for perjury or something worse. Don Kennedy was not lionized but he was generally welcomed.

Part of that I think is a function of personalities. Mac was an academic and was unused to the kind of battering that often goes with participation at the legislative hearing. Nor was he as verbally facile whereas Don Kennedy was extremely engaging and able to be humorous without becoming the guy who told the jokes. A witness can't

be the guy who tells the jokes. The chairman tells the jokes. But you can be lighthearted and humorous in a self-deprecating way. Don Kennedy had those skills, still has those skills, and he generally softened the atmosphere in the hearing room. There were exceptions. One I remember quite vividly because it was the last one in which I participated.

It was before a committee chaired by Senator Tom Eagleton of Missouri, who had briefly been the vice-presidential nominee on the McGovern ticket and then had to withdraw. Don Kennedy was the primary witness, I accompanied him. Kennedy went out of his way to say something about this being my last hearing. I don't know whether it was that or something else but Eagleton immediately made me the witness. He wanted to know, on the record, where I had been before I came to FDA, and I said I'd been at the university.

"Before that."

"Covington and Burling."

"And what did you do at Covington and Burling?"

"Well, I worked with Tommy Austern and Stan Temko and I did food and drug law."

"And what companies did you represent?"

This went on for about fifteen or twenty minutes. The innuendo in Eagleton's course of questioning was that here somebody inside the very heart of the agency had been a shill or a spy for the pharmaceutical industry. That was never made explicit and there was no assertion that I had ever done anything in my FDA life to benefit anybody or that I had helped when I was a private lawyer. Nobody paid any attention to the

interval of six years when I had been a law teacher.

By the end of the hearing, I was a bit shaken by all of this. Senator Eagleton came up to me and slapped me on the back and shook my hand, and he said, "Sorry I had to do that." He clearly was making a point for the record, at someone's request. He was not accusatory at all off stage. Nonetheless, I come away with an undiminished skepticism of the legislative process.

RT: During your tenure, Dick, were the Device Amendments in process?

RM: Yes indeed. Work had begun on that before. Ted Cooper, the head of the Heart Institute . . .

SJ: Tell us about Ted Cooper, and the Cooper Commission. Their report, on paper, is quite brief, yet we know it was highly influential.

RM: Yes.

SJ: It's underwhelming.

RM: It is pretty underwhelming, but I think that's a stylistic criticism. It doesn't look like the kind of report that would be produced today if somebody were chartered to address the adequacy of the current law with respect to a major problem. Of course, if the Cooper Committee were reincarnated to do something about how should the law be

revised to regulate genetically engineered organisms, it would provide a lot of detail along with some synthetic advice. But the Cooper Committee report is a dozen pages, something less than that. It's a set of conclusions. It says in substance that several people got together and thought about this for a long time around the table, and this is where they came out.

SJ: That's the gist of it. But there's little in the way of actual documentation to tell us more about the evolution in their thinking.

RM: No, that is right, but the key message was that a lot of smart people had been around the table, and this represented their consensus judgment. It also reflected what the regulated industry would agree to even though they had not been involved in the Cooper Committee report. The process couldn't work that way today. But there was a lot of, you might say, front-end buy-in to what the legislative scheme should look like. And it is embodied in the Cooper Committee report.

SJ: What was Dr. Cooper like? Did you know him?

RM: I don't know him very well. I was often in the room with him. He was a very small man. He's dead now. And very competent, but not imperious. You know, he would make statements that you wouldn't disagree with unless you were pretty smart or very certain. He had the kind of reputation that assured it would not come out of Cooper's mouth unless it was right. He had a lot of achievements so he could trade on

his deserved reputation rather than on personal presence in a meeting. He was barely over five feet tall, but he was intellectually much taller than almost anybody else in the room. In a quiet, careful way he could convince you that he knew what he was talking about. I have no doubt that he was influential in framing the content of the Cooper Committee report, but there surely would have been other people. I dare say Bill Goodrich had some hand in it because it was the nature of the process that they could consult with people in the agency about what the law ought look like.

The report's starting place was that you can't do for devices what you had done for drugs.

SJ: Right.

RM: You can't have a system in which every product requires approval.

RT: I believe you may have had as general counsel a role in developing some revised definitions for the recall classification of devices. Was that something you recall?

RM: No, I don't.

SJ: Was David Link here when you came?

RM: Dave Link was here.

SJ: He was already here.

RM: That's right. He was head of Devices. Larry Pilot was his deputy.

SJ: But they were up in the Commissioner's office, right? They were still special assistants?

RM: No. They were a separate bureau by the time I got here.

SJ: Okay.

RM: I think that they became a bureau in '74 maybe, something like that. There were six bureaus when I got here, and Link headed one of them.

Anyway, the issue having to do with recalls did surface, but my work on the device amendments to a large extent concluded with their passage in the middle of 1976. I spent a huge amount of time in '75 and '76 on the bill negotiating with -- I'm trying to think of her first name; it could be Anita but I'm not sure -- Johnson was her last name. She was sort of a consumer advocacy person. They had two or three people from the device industry. And hosting the sessions was Steve Lawton, who was counsel to the Health Subcommittee chaired by Paul Rogers. It was in the House, not in the Senate, that not only the basic architecture but the actual text of the Medical Device Amendments was hammered out. That, along with the drug lag and the Senator Kennedy hearings, took more of my time than anything else. I enjoyed that part of the legislative process

enormously and I thought it was carried out quite professionally. Rogers was good in wanting to hear from people who knew, that is, from ostensible experts. We spent a lot of time -- Linda Horton, working with me here spent a lot of time trying to fashion what we understood would be the "constitution" for device regulation which would govern devices for a long time to come.

RT: I was thinking of the establishment of the three classifications for devices, classes one, two, and three.

RM: Right.

RT: I wondered if you were involved in that.

RM: Well, I was involved in fashioning the language that makes provision for that arrangement, but the decision to have that arrangement was recommended by the Cooper Committee in 1970 and was clearly a starting premise for development of legislation by the end of 1974. By the time I got there in 1975, that was not a debatable proposition. That was part of the, you know, fundamental architecture of this law.

SJ: You were talking about the law on its way toward passage and the need to conduct some last-minute consumer negotiations. Do you feel like you were responsible for helping really push that through?

RM: If the question is, was it certain to pass, no. I think it was not certain to pass. Were the chances of its passage pretty good? Yes. A lot depended on the position of the Ford Administration. This was a Republican administration. Their constituencies did not support more regulation of health-care products. But the administration, at the NEW level, supported the legislation, and the White House didn't interfere. However, the White House took no pleasure in its passage. The best evidence of that is a photograph that was given to me on my retirement which shows the signing ceremony in the White House of the Medical Device Amendments. Dave Link, Linda Horton, and others, who'd worked long and hard, expected to be invited to the Rose Garden ceremony. The photo shows just four people in the room: Mac Schmidt, Ford, David Matthews, and a summer intern in the White House. That was it.

SJ: The intern is the fourth person?

RM: That's the fourth person in the picture. And there was no White House fanfare.. A press announcement something like, "Ford today signed a bill on medical devices." But there was no major press release. The administration was taking no pride in it.

SJ: I'm trying to do some research on the early history of the Devices Amendment, and you may be right. There may not have been. I've been trying to make a case that cardiac pacemakers and mechanical heart valves had begun to need regulation in the business environment they were in. Cardiac pacemakers had had some problems, in particular. But the valve industry could have eventually . . . I mean, it's not clear that they needed

the legislation to help control their problems.

RM: Yeah, I think that's probably right. I think the industry's position was a combination of "we need to appear to be more comprehensive," and "it's going to happen, so let's get it done now when the heat's not so intense as it might be later." But I can't put myself in the position of those people.

SJ: So the Dalcon Shield was not critically important?

RM: No.

SJ: I think that was before the problems with the Bjork Shiley valves.

RM: I think it was a little bit before. I don't remember wrestling with any legal question. Probably the Dalkon Shield was on the legislative agenda.

SJ: Do you perceive that it was a more routine piece of legislation than the others had been?

RM: I think that's my impression, that there wasn't a groundswell of constituent outrage. It was not at all clear how many people in Congress thought about the problem. I think had it not been for Paul Rogers, and Ted Kennedy, I think the legislation probably might not have passed then, but probably would have eventually. Rogers was determined, and

Kennedy was determined. They had staff that were equipped to surmount any obstacles in their way.

RT: If you'd like to, we can close now with a continuation at another time, and get this part transcribed in the meantime.

RM: Well, let's go for another ten minutes and see what topics we can identify.

RT: Okay. I think there was some concern about advisory committees and when those were closed and when they were not. Was that a general counsel interest?

RM: Definitely. Advisory committees had come to play a really important role in the deliberations of the agency. Dr. Crout had introduced them in the Bureau of Drugs as a mechanism for leavening the internal assessment process. He thought that if you had people who were experts in patient treatment, you might get a little bit less conservative assessment of the drug applications than the old line employees were providing. Advisory committees were a central feature of the over-the-counter drug review as Peter Hutt had designed it. And advisory committees were, by statute, a mandatory feature of the implementation of the Device Amendment, e.g., how you got devices into one of these three categories. And it was how you then made decisions about what you were going to do about the devices already in the particular categories.

So, and by 1976, I think that advisory committees were a fairly well-established instrument for decision-making within FDA. I suspect that there were employees who

were not happy with having these outside kibitzers in second-guessing what they'd done, but I think people like Dave Link, for example, who was trying to start a program from scratch, welcomed the advisory committees. It was a way of getting help that the government couldn't afford to provide.

But as they were first established, the committees functioned with a high degree of secrecy. They didn't meet much in open session. Peter Hutt feared that if their deliberations were entirely open to the public, that the industry would not play and would object to the whole process. So there was assurance of protection for trade-secret and confidential commercial information. And the more critical issue was confidentiality for the deliberative portions of the meeting, when the advisory committee members are making up their minds about what to recommend to the agency.

The agency's original position -- I think I'm correct on this -- was that these deliberative portions of the meetings were the functional equivalent of an internal memorandum from a staffer to the Commissioner of Food and Drugs. Under the Freedom of Information Act, you can keep that kind of memorandum confidential. By analogy, FDA argued, it should be able to keep a deliberative discussion of a committee that is recorded on the tape recorder confidential. If it is preparatory to the formation of recommendations to the official with legal authority to make the decision.

Then Congress passed -- and I can't remember the date -- the Government in the Sunshine Act, which was really aimed at multi-member agencies like the Federal Trade Commission, which makes decisions collegially. The purpose of the Government in the Sunshine Act, among others, was to see to it that these collegial discussions of what are we going to do about a problem, ending with a vote, "We're going to do X or Y," were to

be accessible to the public. They still have to be. So when the Federal Communications Commission makes a decision about the allocation of radio spectrum, all of the commissioners have to come and sit around a table and vote in public as to what they're going to decide to do. There's a fair amount of preparatory work, but there are significant limitations on the private kinds of conversations commissioners can have with one another. You may meet one another in the hallway, "I think we ought to be doing A about X." Well, that exchange may not be covered. But if you meet three of your fellow commissioners at the water fountain, such a conversation cannot take place.

Well, to make a long story short, the Sunshine Act is designed to make those confidential hallway conversations impossible to put everything of a deliberative sort on the public record. There is language in the Sunshine Act that would suggest that it applied to advisory committees as well. I think that was the only legitimate reading of the statute. We took the position, we in General Counsel, that the agency's advisory committees could continue to meet in private when they're talking about the confidential data provided by the manufacturer. But when they are deliberating about what they're going to recommend to the agency, that has to be in public session.

Well, the people in the bureaus, Dave Link and others, were apoplectic. They thought committee members would not work for the agency anymore. "They're going to go home." And then we began to try to get word, maybe stimulated by FDA staffers, from some members of advisory committees that they would decline to continue to serve. Some telephone calls were unequivocal on that point. "If we have to meet in open session, you can count me out." How many committee members actually ended up resigning, I don't know. Gary Yingling, who oversaw the over-the-counter drug review,

Bill Vodra, who would assist other advisory committees in the Bureau of Drugs, and Arthur Levine, who dealt with the biologics advisory committees, and perhaps Ken Baumgartner, who mainly serviced the Device Center, along with Linda Horton, all got called. The next time an advisory committee was scheduled to meet after the agency made its decision about the Government in the Sunshine Act, one of us went and met with the members and said: "We will do our best to protect the civility of your deliberations. We'll try to have a chairman who monitors carefully the discussion so that it is not a free-for-all with the audience. We hope that you'll find that it is possible to deliberate candidly even if your statements are audible to an audience and recorded in a transcript that anybody else can see. But if you feel you have to resign, we'll understand that, and you can go with our thanks and appreciation for the service you provided." We were trying to put out a fire that was threatening to become an inferno but never did. Maybe our reaction was a little overstated as well. Certainly the committees' reaction was. It was a hot controversy for about six months.

As we worked your way through the scheduled advisory committee meetings, we were able to develop a memorandum to advisory committee members -- maybe one from each center; I'm not sure -- saying, "This is it." But we really needed to be available in person to answer questions. "How could Congress do something like this?" Of course we could say Congress dropped the initiative, this is not the first time." We also tried to explain so the members understood where we were coming from, that this was not an edict from the Commissioner designed to expose them to embarrassment, but was a law that the Commissioner recognized the agency had to comply with. I suspect there were similar brushfires across the Executive Branch in other agencies which relied on advisory

committees.

RT: Do you recall who in the Congress was the sponsor of the legislation?

RM: Well, Senator Metcalf of Montana was the author of an earlier law, the Advisory Committee Act, but I don't know who led the fight for the Sunshine Act.

I don't think Metcalf ever thought about FDA or knew anything about FDA. He was concerned about advisory committees in other parts of the government. I hazard a guess that he was concerned about advisory committees in those parts of the government that were responsible for management and access to the nation's natural resources, e.g., mining rights, timber rights, and the like, which would be of great interest to people in Montana. His concern was that the people that government is supposed to regulate are too close to the people who do the regulating. He wanted to open that process up. And if it means that we have to get rid of some advisory committees, so be it. The fact that the baby would go out with the bathwater didn't, I think, matter to Metcalf or people who supported the legislation.

RT: You initially served under Commissioner Schmidt. Is that right? How long did you serve under his successor?

RM: Yes. I can't remember the date when Mac left. I came in May of '75. Mac was gone by the end of '76, maybe a tad earlier. I think he calibrated his departure to the academic schedule at the University of Illinois, to which he returned. Don Kennedy

would have been appointed sometime in the spring, probably March of ’77, because President Carter was to be inaugurated and he was to appoint HEW Secretary [Joe] Califano, and Califano in turn would have selected Don Kennedy. Kennedy was on board by April of ’77. So through the end of July, I saw him every day and worked with him closely.

TAPE 2, SIDE B

RM: I worked with Kennedy very closely. I recall a hearing we attended, chaired by [Senator] Pat Leahy, then chairman of the Agriculture Appropriations Subcommittee in the Senate. The ranking minority member was [Senator] Richard Lugar from Indiana. They are both very nice and decent people. And we sat around a table half the size of this one for the hearings. The whole atmosphere was very different than the usual courtroom-like setting with the presiding legislators several levels above you.

Don Kennedy and I currently co-chair a program at the National Academy of Sciences on science and law. We’ve remained in contact and are close collaborators.

RM: Had I known that Donald Kennedy was going to be Schmidt’s successor, and had I known how well I would get along with him, I might have tested the University of Virginia’s two-year-leave policy and stayed longer. But that knowledge came to me late, and, more critically, it came to me after we had begun building a house in Charlottesville. We had construction underway back in Charlottesville and we could not afford to maintain a house in Rockville and continue to build a house in Charlottesville. So come

the end of July, we departed and I went back to teach.

SJ: That's a good place to stop.

RT: Yes. Well, Richard, we appreciate very you're your being available for this oral history interview, and we wish you continued success in your pursuit of education in the field of law.

RM: Delighted to be with you.

SJ: There are still several things we'd like to cover with you, so . . .

RM: Well, I think it would help me if you had a list of topics you'd like me to sort of refresh my recollection on.

SJ: Sure.

RM: You could do that with an e-mail.

RT: I'll be glad to send you an e-mail to say, "We'd like the next time to talk about X, Y, and Z."

SJ: And likewise, you can send us a message regarding what you want us to include.

END OF INTERVIEW